JUL - 5 2001

K003818

Attachment II

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: Titanium Abutment Heads
Common / Usual Name: COC Titanium Abutment Heads
Proprietary Name:

Establishment Registration Number:

Classification: Class III, Reg. # 872.3640

Performance Standards: N/A

Substantial Equivalence: COC Titanium Abutment Heads are currently being marketed and distributed by Implant Support Systems, Inc. Implant Support Systems currently holds a 510k for COC Titanium Abutment Heads (510k # K925313)

Material Composition

Abutment Heads -	Titanium., Ti-6A1-4V
Screws -	Titanium., Ti-6A1-4V

Testing conducted to assure safety and effectiveness include but is not limited to:

- Dimensional Verification
- Visual Inspection
- Bioburden
- Material Certification

Intended Use:

The titanium Abutment Heads and Screws are intended for use with the various implants, and are designed for cement-retained restorations where standard crown and bridge techniques are desired. The range of application is from full arch restoration to single tooth replacement. These devices may also be used as a base for transitional appliances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2001

Titan Implants
Ms. Lynette L. Howard
Correspondent
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K003818
Trade/Device Name: Titanium Abutment Heads For IMZ Implants
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 6, 2001
Received: April 9, 2001

Dear Ms. Howard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TITAN IMPLANTS

ATTACHMENT VII

STATEMENT OF INDICATION FOR USE

510(k) Number: K003818 **Page 1 of 1**

Device Name: **Titanium Abutment Heads for IMZ Implants**

Indications for Use:

The titanium Abutment Heads and screws are intended for use with the various implants, and are designed for cement-retained restorations where standard crown and bridge techniques are desired. These devices may also be used as a base for transitional appliances.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003818